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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,643	04/20/2001	Gad Keren	1291-01	2139

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EXAMINER	
FLYNN, AMANDA R	

ART UNIT	PAPER NUMBER
3743	22

DATE MAILED: 07/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,643	KEREN ET AL.	
	Examiner	Art Unit	
	Amanda R. Flynn	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 January 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the left ventricle, the externally coupled energy source and the battery must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 1-11 and 13-20 are objected to because of the following informalities:

- In claim 3, at line 3, the word --is-- should be inserted between "heart" and "above".
- In claim 3, a period is needed at the end of the claim.

- In claims 6 and 7, there is insufficient antecedent basis for the term "said signal".
- In claim 11, at line 8, the word "an" should be replaced with --and--.
- In claim 13, at line 3, the word --is-- should be inserted between "heart" and "above".
- In claim 15, at line 2, the phrase "further comprising the step of" is redundant.
- In claim 15, at line 5, the phrase "is reduced" is redundant.
- In claim 20, the term "fixation element" lacks antecedent basis in the claim from which it depends. Claim 19 refers to "affixation elements".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-11 and 13-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-11 and 13-20 recite an apparatus and method via its attachment to a part of the human body. Specifically, applicant recites, "comprising a shunt implanted in a puncture in a septum..." and similar such language throughout the claims. Claims reciting a portion of, or an attachment to, the human body contain non-statutory subject matter. 1077 OG 24 (April 21, 1987).

Applicant can overcome this rejection by amending claim 1 to recite, "comprising a shunt *adapted to be* implanted in a puncture in a septum..." and adding similar such language to the other offending claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2, 9-11 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,429,144 to Wilk.

Wilk discloses a chronic implant apparatus capable of decreasing pressure in a first portion (left ventricle, LV) of a cardiac structure of a patient comprising a shunt (12) implanted in a puncture ("perforation" or "recess") in a septum (HW) defining the left ventricle of the cardiac structure, whereby a volume of blood sufficient to reduce an end diastolic pressure in said first portion flows across said septum, due to a pressure differential. The shunt disclosed by Wilk is a tubular element having two ends, each end comprising a tissue affixation element in the form of a "spring bias or memory, tending to form the stent into a substantially tubular opened configuration." The tubular element is substantially formed of a biologically inert non-metallic (graft, for example).

The claimed method is anticipated by the normal operation of the device disclosed by Wilk, which entails puncturing the left ventricle vessel wall and implanting a shunt therein to reduce the end diastolic pressure. Wilk discloses selectively permitting flow when a pressure differential between the left ventricle and another chamber of the heart (CA) exists (wherein the pressure differential necessarily exists to allow blood flow through the shunt), whereby shunting

is prevented during ventricular systole (column 3, lines 50-56). Wilk discloses implanting the shunt via a catheter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk.

Wilk discloses the previously described shunt. Wilk discloses one embodiment of the shunt in which the shunt is closed to blood flow during systole (by contraction of the heart muscle) and open to blood flow during diastole to ensure uni-directional flow of blood through the shunt.

Wilk discloses a second embodiment of the shunt, in which the shunt has a passive check valve that closes the shunt to ensure uni-directional flow of blood from the left ventricle.

It would have been obvious to one skilled in the art to provide the shunt disclosed by Wilk, wherein the shunt is closed to blood flow during systole and open to blood flow during diastole, and wherein the closing mechanism is a passive check valve, as taught by a second embodiment of Wilk, to ensure uni-directional flow of blood.

9. Claims 5, 7-8, 15 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of U.S. Patent Number 6,210,318 to Lederman.

Wilk discloses the previously described shunt implanted in a septum and communicating with an area outside the left ventricle to reduce end diastolic pressure as blood flows through the

shunt. Wilk specifies that the shunt may have a check valve to permit flow from the left ventricle. Wilk does not specify that the check valve be a semi-passive check valve. Wilk also does not specify that the shunt include pumping means.

Lederman discloses a shunt and pumping balloon device that is placed in a patient's left ventricle, to assist in the pumping of blood from the ventricle. The device comprises several valves, which may be semi-passive check valves operated by an extracorporeal controller to control the activation of the valves externally from the patient. The pumping balloon (102) is in fluid communication with the shunt (104) and has an input connected to the left ventricle, and an output connected to a volume of lower pressure.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Wilk wherein the check valve is a semi-passive check valve and the shunt includes a pump, as taught by Lederman, to control activation of the valves externally from the patient, and to assist the flow of blood from the left ventricle. The claimed method of decreasing end diastolic pressure is made obvious by the normal use of the device disclosed by Wilk in view of Lederman.

10. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk in view of U.S. Patent Number 6,632,169 to Korakianitis et al.

Wilk discloses the previously described shunt implanted in a septum and communicating with an area outside the left ventricle to reduce end diastolic pressure as blood flows through the shunt. Wilk specifies that the shunt may have a check valve to permit flow from the left ventricle. Wilk does not specify that the check valve be a semi-passive check valve.

Korakianitis et al. disclose a left ventricular assist device that is placed in a patient's left ventricle, to assist in the pumping of blood through the heart and body. The device comprises a semi-passive check valve operated by an intra-corporeal electrical battery so that the entire device can be contained within the body.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the shunt disclosed by Wilk wherein the check valve is a semi-passive check valve, as taught by Korakianitis et al., so that the entire device can be contained within the body. The claimed method of decreasing end diastolic pressure is made obvious by the normal use of the device disclosed by Wilk in view of Korakianitis et al.

Response to Arguments

11. Applicant's arguments filed 01 December 2003 have been considered but are moot in view of the new ground(s) of rejection.

12. Per MPEP, section 2114: "While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)"

13. It is noted that applicant's claims lack sufficient structure to differentiate it from the prior art. Regarding the structural limitations of claim 1, the claim solely requires a shunt capable of being utilized in the manner claimed, even if the prior art device does not disclose such functionality.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda Flynn

Amanda R. Flynn

Examiner
Art Unit 3743

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